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510(k) SUMMARY

DATE: October 1, 2007

SUBMITTER:
Innovative Spinal Technologies, Inc.
111 Forbes Boulevard
Mansfield, MA 02048
Telephone: 508/452-3520
Fax: 508/452-3600

OCT 11 2007

CONTACT PERSON: Gina Yeh

TRADE NAME: Paramount™ Intervertebral Body Fusion Device

FDA CLASSIFICATION / CODE: 888.3080 / MAX

DEVICE DESCRIPTION: The Paramount™ Intervertebral Body Fusion Device is made of PEEK-OPTIMA®. The implant is offered in various widths, heights, angles and lengths to meet individual patient anatomy. The devices are provided sterile and the instruments are provided clean and non-sterile for steam sterilization at the user's facility.

INTENDED USE: The Paramount™ IBF device, when used with autogenous bone graft, is indicated for use in patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Paramount™ IBF devices are to be implanted via a direct posterior or transforaminal approach. The Paramount™ IBF device may be used singly or in pairs in the lumbosacral spine with or without supplemental fixation, such as the Paramount™ Pedicle Screw System.

PREDICATE DEVICES: The predicate devices include: Innovative Spinal Technologies, Inc. Paramount™ VBR System (K062759) and Centerpulse/ Zimmer Spine, Inc. BAK™ Interbody Fusion System (P950002).

PERFORMANCE DATA: The mechanical test results based on ASTM F2077, ASTM F2267, and ASTM F-04.25.02.02 demonstrate that the Paramount™ Intervertebral Body Fusion Device can be expected to perform in a manner substantially equivalent to the predicate devices. In addition, biocompatibility of the device was demonstrated via testing per ISO10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2007

Innovative Spinal Technologies, Incorporated
% Ms. Gina Yeh
Manager, Regulatory Affairs
111 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K072120
Trade/Device Name: Paramount Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 31, 2007
Received: August 1, 2007

Dear Ms. Yeh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Appendix 1

Indication for Use Statement

510(k) Number: K072120

Device Name: Paramount™ Intervertebral Body Fusion Device

Indications:

The Paramount™ IBF device, when used with autogenous bone graft, is indicated for use in patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Paramount™ IBF devices are to be implanted via a direct posterior or transforaminal approach. The Paramount™ IBF device may be used singly or in pairs in the lumbosacral spine with or without supplemental fixation, such as the Paramount™ Pedicle Screw System.

Prescription Use ___X___ (21 CFR 801 Subpart D) or Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janbaie Brie MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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